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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,411	03/01/2002	Gary P. Schroth	9584-030-999	6226

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/087,411

Applicant(s)
Schroth

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 23, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0803 6) ☒ Other: Detailed Action

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DETAILED ACTION

Status of the Application

1. The amendment received on July 23, 2003 has been entered. Claim 2 has been amended. Claims 1-12 are pending and under consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
3. Claims 1-5 are rejected under 35 U.S.C. 102 (b) as being anticipated by Benner (U.S. Patent 5,432,272) (July 11, 1995).

Benner teaches a method of identifying a coded test unit in a plurality of coded test units comprising the step of:

contacting the coded test unit with a decoding oligonucleotide comprising an orthogonal nucleobase under conditions in which the decoding oligonucleotide produces a detectable hybridization signal sufficient to distinguish the coded test unit from the remainder of the plurality of coded test units (Example 2, and Column 2, line 61 to Column 3, line 35).

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Benner teaches a method of decoding a plurality of coded test units comprising the steps of:

- a. identifying a first molecule in the plurality of coded test units ; and
- b. identifying a second molecule in the plurality of coded test units (Example 2, and

Figure 5).

Benner teaches a method, wherein the coded test unit is coded with a decoding oligonucleotide independently comprising an orthogonal nucleobase selected from iso-C, iso-G, K, X, or H (Column 3, lines 6-35).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-12 are rejected under 35 U.S.C. 103(a) as being obvious over Benner (U.S.

Patent 5,432,272) (July 11, 1995) in view of Southern (U.S. Patent 6,054,270) (April 25, 2000).

Benner teaches the method of claims 1-5 as described above.

Benner also teaches the method, wherein each coded substrate comprises an oligonucleotide test moiety (Example 2, and Column 2, line 61 to Column 3, line 35).

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Benner also teaches the method, wherein a single polynucleotide comprises the test moiety and the coding oligonucleotide, and wherein a first polynucleotide comprises the test moiety and a second polynucleotide comprises the coding oligonucleotide (Example 2).

Benner does not teach the method, wherein the coded test unit comprises a solid substrate.

Southern teaches the method, wherein the coded test unit comprises a solid substrate (Examples 1, 3, and 7, and Column 8, line 59 to Column 9, line 36).

Benner does not teach the method, wherein the plurality of coded substrate is an array.

Southern teaches the method, wherein the plurality of coded substrate is an array. (Column 1, line 30 to Column 2, line 33 and Examples 3, 6, and 7).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine a method, wherein the coded test unit comprises a solid substrate and wherein the plurality of coded substrate is an array of Southern In the orthogonal nucleobase hybridization method of Benner, since Southern states, "This invention provides a new approach which produces both a fingerprint and a partial or complete sequence in a single analysis, and may be used directly with complex DNAs and populations of RNA without the need for cloning (Column 1, lines 30-33)". Moreover, further motivation is provided by Benner as Benner states, "it might be possible for each non-standard pyrimidine to recognize uniquely its complementary purine with high fidelity (Column 3, lines 26-28)". An ordinary practitioner would have been motivated to substitute and combine a method, wherein the coded test unit comprises a solid substrate and wherein the plurality of coded substrate is an array of

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Southern In the orthogonal nucleobase hybridization method of Benner, in order to achieve the express advantages, as noted by Southern, of an invention which provides a new approach which produces both a fingerprint and a partial or complete sequence in a single analysis, and may be used directly with complex DNAs and populations of RNA without the need for cloning and also in order to achieve the express advantages, as noted by Benner, of an invention which provides a possibility for each non-standard pyrimidine to recognize uniquely its complementary purine with high fidelity.

Response to Amendment

6. In response to amendment, all previous 102(b) and 103(a) rejections are hereby properly maintained.

Response to Arguments

7. Applicant's arguments filed on July 23, 2003 have been fully considered but they are not persuasive.

Applicant argues (page 5, line 1 to fourth paragraph) that 102(b) rejection based on Benner should be withdrawn because Benner does not teach the main feature of the claimed invention "coded test unit". This argument is not persuasive. The specification defines the term "coded test unit" (Page 3, first paragraph) as the "units can be molecules comprising coding oligonucleotides". MPEP 2111 states, "Claims must be given their broadest reasonable

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interpretation. During patent examination, the pending claims must be “given the broadest reasonable interpretation consistent with the specification”. Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)”. In this case, Benner expressly teaches “coded test unit” (Example 2, Column 8, line 40 to Column 9, line 6). Moreover, any template/primer complex of Benner can be broadly interpreted as “coded test unit”.

Applicant also argues (page 5, last paragraph) that Benner teaches an extra step of polymerization of nucleic acids and therefore it is not a proper prior art. This argument is not persuasive, especially in the presence of open “comprising” language of the claims, any additional step(s) or material (s) can be added to the claimed invention and any reorientation of the method step(s) is also permissible.

In response to applicant's arguments (page 7, second paragraph) against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant also argues (Page 7, third to fourth paragraph) that 103(a) rejection should be withdrawn because there is no motivation to combine the references. This argument is not persuasive, especially in the presence of strong motivation provided by Southern as Southern

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states, "This invention provides a new approach which produces both a fingerprint and a partial or complete sequence in a single analysis, and may be used directly with complex DNAs and populations of RNA without the need for cloning (Column 1, lines 30-33)". Moreover, further motivation is provided by Benner as Benner states, "it might be possible for each non-standard pyrimidine to recognize uniquely its complementary purine with high fidelity (Column 3, lines 26-28)".

In view of the response to arguments, all previous 102(b) and 103(a) rejections are hereby properly maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

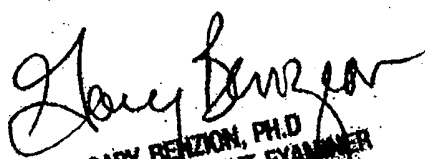
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

September 15, 2003


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
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